

**REMARKS**

Claims 1, 3-16, 18-31, 33, 34, 36-41, 43, 44, 46-57 and 59-65 are pending in the present application. By virtue of this response, claims 41 and 50 have been amended. Accordingly, claims 1, 3-16, 18-31, 33, 34, 36-41, 43, 44, 46-57 and 59-65 are currently under consideration. Amendment of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

***Claim Rejections – 35 U.S.C. § 112, First Paragraph***

Claims 41, 43, 44 and 46-56 stand rejected under 35 U.S.C. 112, first paragraph. The Examiner alleges that the specification, while being enabling for methods of treating a superficial bladder tumor in the mucosal layer of the luminal surface of a bladder by contacting the luminal surface of the bladder with a transfection composition comprising (i) a polynucleotide; (ii) a cationic lipid, a cationic polymer or a dendrimer, or combinations thereof; and (iii) a solubilized cholesterol preparation comprising cholesterol solubilized with a cyclodextrin, wherein the polynucleotide is capable of expressing a protein selected from the group consisting of interleukin-1 (IL-1), interleukin-2 (IL-2), interleukin-12 (IL-12), interleukin-13 (IL-13), interleukin-18 (IL-18), interferon-alpha, interferon-beta, interferon-gamma, granulocyte-macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), p53, and an antagonist of vascular endothelial cell growth factor (VEGF), does not reasonably provide enablement for methods of treating bladder cancer in the muscular layer of the bladder.

Without acquiescing to this rejection and in an effort to expedite prosecution, Applicant has amended claims 41 to recite a method for treating a superficial bladder cancer. Support for this amendment may be found in the specification on page 15, lines 30-32; page 34, lines 23-24 and in Figure 6. In view of this amendment, the rejection has been rendered moot. Accordingly, Applicant respectfully requests withdrawal of this § 112, second paragraph rejection of claim 41. Since claims 43, 44, and 46-56 recite the method of claim 41, it follows that the dependent claims reciting the method to treat superficial bladder cancer are enabled as well.

In addition, the Examiner alleges that the specification is not enabling for methods of treating superficial bladder cancer with nucleic acids encoding a tissue inhibitor of metalloproteinases (TIMP).

Without acquiescing to this rejection and in an effort to expedite prosecution, Applicant has amended claims 50 to delete nucleic acids encoding a tissue inhibitor of metalloproteinases (TIMP). In view of this amendment, the rejection has been rendered moot. Accordingly, Applicant respectfully requests withdrawal of this §112, second paragraph rejection of claim 50.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 578762000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 8, 2007

Respectfully submitted,

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